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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,936	11/05/2001	Robert F. Kaiko	200.1102CP2	9880

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EXAMINER
WARE, TODD

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/992,936	Applicant(s) KAIKO ET AL.	
	Examiner Todd D Ware	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-10,12-32 and 34-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3,6-10,12-32 and 34-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of request for extension of time (granted) and amendment both filed 8-12-02 is acknowledged. Claim 11 has been canceled and claims 1, 19-20, 27, and 32 have been amended and new claims 37-40 have been added as requested. Claims 1, 3, 6-10, 12-32, and 34-40 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3, 6, 8-32, and 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crain et al (5,512,578; hereafter '578) in combination with Hynes (EP 0 193 355; hereafter '355) and further in combination with Oshlack et al (5,472,712; hereafter '712) **or** Crain et al (5,512,578; hereafter '578) in combination with Raffa et al (5,336,691; hereafter '691) and further in combination with Oshlack et al (5,472,712; hereafter '712) **or** Crain et al (5,512,578; hereafter '578) in combination with Dudzinski (4,237,140; hereafter '140) and further in combination with Oshlack et al (5,472,712; hereafter '712).

The instant claims are directed toward combination opioid agonist/antagonist/acetaminophen controlled release oral formulations and a method for

treating pain with the combination opioid agonist/antagonist/acetaminophen oral formulations.

'578 teaches oral compositions comprising opioid agonists and opioid antagonists that may be used for treating opioid abuse. '578 also teaches a method treating pain with the disclosed composition. '578 does not teach the inclusion of non-narcotic analgesics in the disclosed formulation or a controlled release formulation.

'355, '691, and '140 all teach inclusion of non-narcotic analgesics, such as acetaminophen in narcotic formulations. These references show that the interaction between the active agents is superadditive or synergistic. None of these references controlled release formulations as required in the instant claims.

'712 teaches controlled release opioid formulations that provide controlled release in accordance with the instant claims.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include non-narcotic analgesics in the formulation of '578 in an effort to provide enhanced analgesia by means of producing analgesia though non-opioid antinociceptive pathways. Furthermore, since the interactions are synergistic, it would have been obvious to one skilled in the art at the time of the invention to use doses that would otherwise be subtherapeutic if given alone with the motivation of maintaining low instance of side effects while maintaining an analgesic dose. Furthermore, it would have been obvious to one skilled in the art at the time of the invention to provide controlled release formulations of the obvious previous compositions to reduce the frequency of administration.

Response to Arguments

3. Applicant's arguments filed 8-12-02 have been fully considered but they are not persuasive. Applicant argues that the references are not combinable since '578 only contemplates immediate release formulations and does not mention controlled release formulations while '712 only contemplates controlled release and does not mention immediate release formulations. Applicant therefore argues that there is no motivation to combine the references. In response, the Office Action of 2-4-02 stated that the motivation to combine the references is to reduce the frequency of administration.

4. Claims 1, 3, 6, 8-32, and 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al (4,457,933; hereafter '933) in combination with Hynes (EP 0 193 355; hereafter '355) and further in combination with Oshlack et al (5,472,712; hereafter '712) **or** Gordon et al (4,457,933; hereafter '933) in combination with Raffa et al (5,336,691; hereafter '691) and further in combination with Oshlack et al (5,472,712; hereafter '712) **or** Gordon et al (4,457,933; hereafter '933) in combination with Dudzinski (4,237,140; hereafter '140) and further in combination with Oshlack et al (5,472,712; hereafter '712).

'933 also teaches opioid agonist and opioid antagonist composition and methods for treating pain. '933 does not teach inclusion of non-narcotic analgesics or a controlled release formulation in the taught formulations.

'355, '691, and '140 are all relied upon for all that they teach as stated previously.

'712 teaches controlled release opioid formulations that meet the instant claims.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include non-narcotic analgesics in the formulation of '933 in an effort to provide enhanced analgesia by means of producing analgesia though non-opioid antinociceptive pathways. Furthermore, since the interactions are synergistic, it would have been obvious to one skilled in the art at the time of the invention to use doses that would otherwise be subtherapeutic if given alone with the motivation of maintaining low instance of side effects while maintaining an analgesic dose. Furthermore, it would have been obvious to one skilled in the art at the time of the invention to provide controlled release formulations of the obvious previous compositions to reduce the frequency of administration.

Response to Arguments

5. Applicant's arguments filed 8-12-02 have been fully considered but they are not persuasive. Applicant argues that the references are not combinable since '933 only contemplates immediate release formulations and does not mention controlled release formulations while '712 only contemplates controlled release and does not mention immediate release formulations. Applicant therefore argues that there is no motivation to combine the references. In response, the Office Action of 2-4-02 stated that the motivation to combine the references is to reduce the frequency of administration.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crain et al (5,512,578; hereafter '578) in combination with Hynes (EP 0 193 355; hereafter '355) in combination with Gauthier et al (5,552,422; hereafter '422) and further in combination

with Oshlack et al (5,472,712; hereafter '712) **or** Crain et al (5,512,578; hereafter '578) in combination with Raffa et al (5,336,691; hereafter '691 in combination with Gauthier et al (5,552,422; hereafter '422) and further in combination with Oshlack et al (5,472,712; hereafter '712) **or** Crain et al (5,512,578; hereafter '578) in combination with Dudzinski (4,237,140; hereafter '140) in combination with Gauthier et al (5,552,422; hereafter '422) and further in combination with Oshlack et al (5,472,712; hereafter '712).

'578, '355, '691, and '140 are all relied upon for all that they teach as stated previously. None of these references teaches inclusion of an additional non-opioid drug as required in instant claim 7.

'422 teaches combination of COX-2 inhibitors with acetaminophen and opioids (C 9, L 25-C 10, L 14).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine these teachings and include a COX-2 inhibitor in the above obvious formulations to provide enhanced analgesia by means of producing analgesia though non-opioid and non-acetaminophen antinociceptive pathways.

Response to Arguments

7. Applicant's arguments filed 8-12-02 have been fully considered but they are not persuasive. Applicant relies upon arguments that the immediate release formulations are not combinable with the controlled release formulations on the basis that there is no motivation to combine the references. However, as stated *supra,* the motivation to combine the references is to reduce the frequency of administration.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al (4,457,933; hereafter '933) in combination with Hynes (EP 0 193 355; hereafter '355) in combination with Gauthier et al (5,552,422; hereafter '422) and further in combination with Oshlack et al (5,472,712; hereafter '712) **or** Gordon et al (4,457,933; hereafter '933) in combination with Raffa et al (5,336,691; hereafter '691) in combination with Gauthier et al (5,552,422; hereafter '422) and further in combination with Oshlack et al (5,472,712; hereafter '712) **or** Gordon et al (4,457,933; hereafter '933) in combination with Dudzinski (4,237,140; hereafter '140) in combination with Gauthier et al (5,552,422; hereafter '422) and further in combination with Oshlack et al (5,472,712; hereafter '712).

'933, '355, '691, and '140 are all relied upon for all that they teach as stated previously. None of these references teaches inclusion of an additional non-opioid drug as required in instant claim 7.

'422 teaches combination of COX-2 inhibitors with acetaminophen and opioids (C 9, L 25-C 10, L 14).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine these teachings and include a COX-2 inhibitor in the above obvious formulations to provide enhanced analgesia by means of producing analgesia though non-opioid and non-acetaminophen antinociceptive pathways.

Response to Arguments

9. Applicant's arguments filed 8-12-02 have been fully considered but they are not persuasive. Applicant relies upon arguments that the immediate release formulations are not combinable with the controlled release formulations on the basis that there is no

motivation to combine the references. However, as stated *supra,* the motivation to combine the references is to reduce the frequency of administration.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 3, 6-32 and 34-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No. 6,277,384. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to methods of use for oral opioid agonist/antagonist compositions. Furthermore, the method of 6,277,384 discloses the compositions of the instant application.

12. Claims 1, 3, 6-32 and 34-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36

of copending Application No. 09/503,020. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to methods of use for oral opioid agonist/antagonist compositions. Furthermore, the method of Application No. 09/503,020 discloses the compositions of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

13. Applicant's arguments filed 8-12-02 have been fully considered but they are not persuasive. Applicant has stated that a terminal disclaimer will be filed upon indication that the claims are otherwise allowable.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Currently, no claim is allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 8:30 AM - 6 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) for regular communications and (703) for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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October 25, 2002